

REMARKS

Claims 1, 4-15, and 19-36 are presented for the Examiner's review and consideration. In this response, claims 1, 4-7, 15, 19-22, 26, 28, 30-31 have been amended; claims 16-18 have been cancelled; and claims 34-36 have been added. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §103 Rejections

The following claims were rejected as being unpatentable under 35 U.S.C. §103(a) over the cited references:

Claims 1 and 4-7 over Waugh et al. (US Pat. 3,869,731) ("Waugh") in view of Whiteside (US Pat. 4,474,177) ("Whiteside");

Claim 8 over Waugh in view of Whiteside in view of Sherwin (US Pat. 3,750,652);

Claims 9-10 and 13-14 over Waugh in view of Whiteside in view of Shapiro (US Pat. 4,565,192);

Claims 9-12 over Waugh in view of Whiteside in view of Waddell (US Pat. 6,174,314);

Claims 15-18 and 21-25 over Techiera (US Pat. 6,106,529) in view of Waugh in view of Whiteside;

Claim 19 over Techiera in view of Waugh in view of Whiteside;

Claim 20 over Techiera in view of Waugh in view of Whiteside in view of Sherwin; and

Claims 26-33 over Techiera in view of Matsen, III et al. (US Pat. 4,979,949) in view of Whiteside.

Initially, as noted above, claims 16-18 have been cancelled, rendering the rejection of these claims moot. For reasons set forth below, Applicant respectfully submits that these rejections should be withdrawn.

Claim 1 and Dependents

Waugh discloses a “long medial parapatellar incision” and an inverted and laterally displaced patella, providing “excellent exposure of the anterior aspect of the entire knee joint”. (Col. 4, lns. 51-54). The same approach is taken in Whiteside—“Operatively, the usual surgical approach is made. After the anterior aspect of the knee is exposed...”. (Col. 7, lns. 64-65). Indeed, the “usual approach” described in these references was a complete exposure of the distal portion of the femur, and the proximal portion of the tibia, with the patella being moved laterally and inverted to completely expose the knee joint.

This approach was physically traumatic, and greatly increased recovery time, as compared with the minimally invasive methods first disclosed in the instant invention. More particularly to the claimed invention, however, a minimally invasive approach requires methods not disclosed in the prior art for preparing bones of the joint for replacement implants.

Claim 1 has been herein amended to clarify that bones are not completely exposed, as in the prior art, when they are cut to receive an implant portion, reciting specifically “angularly disposing the cutting tool along the guide surface in order to cut a section of the bone wider than the width of the guide, at least a portion of said cut section of bone being located in the interior of the body with respect to the incision”. This technique, used inside the body, is novel, and was not required in the prior art, where the entire exposed joint surface was easily cut using a non-angled blade. Support for the claim amendments may be found, at least, in Fig’s. 8, 13-14, 21-24, and related discussion in the specification.

Matsen is cited, in the rejection of claim 26, as the sole reference disclosing an angled saw blade, in Fig. 3, and in Col. 23, lns. 43-52 which states:

“In one preferred embodiment, the saw guide is crescent shaped so that it can be used near a bone end in a manner that minimally interfaces with the overall view 45 of the bone. The crescent shape allows the guide to be placed relatively close to the bone and allows the saw blade to approach the bone from a range of angles. The surgeon can see the entry point of the blade. While the saw guide is shown positioned and oriented for an ante- 50 rior cut, the same guide is used to guide the saw blade in each of the cut planes.”

Applicant notes that in Matsen, as can readily be seen in Fig's. 3 and 19, a large robotic arm holds and positions the guide. Thus, the problem to be solved in Matsen is positioning the bulky robot arm so that the surgeon can see the work area. An angled cut similarly allows the surgeon to avoid the robot arm. Thus, the purpose of angling a blade in Matsen has no relation to the purpose in the instant invention. Moreover, the cut is formed completely exterior or outside of the body with respect to the incision. In addition, as is clearly visible in Fig. 19 of Matsen, the guide is wider than the section of bone to be cut.

Thus, the guide and technique of Matsen fails to disclose the elements in claim 1 recited above, and further, could not be used in a minimally invasive procedure such as is otherwise claimed and disclosed in accordance with the invention.

Cited references Waugh and Whiteside fail to remedy the deficiencies of Matsen. Moreover, as outlined above, the references are not relevant in the context of a reduced size incision, the bones of the joint being fully exposed, exterior to the skin.

Applicant further notes that Whiteside is cited to show completing a cut after a guide is removed. However, as stated in the cited portion of Whiteside, "Cutting guide 80 is removed and the rough cut is completed if the surgeon was not able to completely cut through the condyles with cutting guide 80 attached." Thus, Whiteside does not disclose completing a cut inside the body, and does not suggest completing cuts due to a short guide surface.

Similarly, Whiteside discloses cutting a small ridge left over after using a planer (Col. 10, lns. 5-10), again an operation described only for an exposed bone. Further, Whiteside teaches away from a reduced size instrument—"Planar surface 121 is preferably large enough so that the lateral aspects of the femoral condyles are not left with a ridge."

Accordingly, Applicant respectfully submits that claim 1 is patentable over Waugh in view of Whiteside, as cited in the rejection, and further in view of Matsen with respect to the incorporation of subject matter from claim 26 into claim 1. As claims 4-14 depend from claim 1, these dependent claims necessarily include all the elements of the base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references at least for the same reasons.

Claim 15 and Dependents

The rejection states that Techiera discloses positioning first and second implant portions against the bone, citing Col. 3, lns. 37-41, which states: “The present invention is a tool which simplifies the procedure of preparing the distal femoral end for a prosthetic implant by allowing the surgeon to conveniently size the femur and position components in relation to the epicondylar axis using a single instrument.”

The rejection further cites Col. 1, lns. 33-38 for connecting first and second portions of the implant: “Numerous specially aligned cuts at the bone ends are necessary in order to install the prosthetic components with correct spacing, alignment and tensioning to prevent improper kinematics from arising as the joint rotates in use, and to avoid the occurrence of accelerated wear patterns or possible joint dislocation.”

Applicant respectfully disagrees that this disclosure relates to first and second implant portions. The rejection additionally states that Techiera does not disclose positioning a first portion of a total knee replacement component against the cut bone, and subsequently positioning a second portion of the total knee replacement component against the cut bone; and connecting the first and second portions of the total knee replacement component after both portions have been positioned against the cut bone, each of the first and second portions of the total knee replacement component having an articulating surface, citing instead Waugh.

As referenced in the rejection, Waugh states: “When correct bone preparation has been determined by use of both trial prostheses, the femoral prosthesis may be implanted.” (Col. 6, lns. 11-13), and “After implantation of the prosthesis, the knee is slowly returned to full extension. (0° flexion). During the elevation from flexion to extension, the surgeon must feel the pressure required to compensate for varus or valgus, remembering that excessive pressure in either direction will result in migration of the uncured cement.” (Col. 6, lns. 43-49).

The cited portions of Waugh refer to first using more than one trial, then femoral, and then tibial prosthesis. There is thus not disclosed in Waugh connected implant portions connected to “the bone”. Clearly a femoral and tibial implant are not connected to the same bone. Additionally, the specification, and the well accepted convention in the art is to refer to the joint replacement component as the implant, while a trial or provisional trial is not intended to be left

within the body, and thus is not an implant. Applicant thus disagrees that Waugh discloses the claimed elements.

To further clarify the invention, claim 15 has been amended herein to recite, *inter alia*, positioning a first portion of a total knee replacement component against cut bone *of one side of a joint*, and subsequently positioning a second portion of the total knee replacement component against the cut bone *on the same side of the joint*; and *affixing* the first and second portions of the total knee replacement component *together* after both portions have been positioned against the cut bone *within the body*, each of the first and second portions of the total knee replacement component having an articulating surface.

Neither Techiera nor Waugh disclose or suggest, at least, the cited elements of claim 15.

Moreover, as discussed with respect to Waugh and Whiteside, Techiera is similarly directed to fully exposed knee bones in that there is no disclosure of a reduced size incision or other minimally invasive techniques, permitting an assumption that the standard techniques for resection of the distal end of the femur were applied, as described above for Waugh. This is further supported by Fig. 1 of Waugh, and with respect to sighting element 65 and other markings on the device of Techiera, which must be exposed outside of the body in order to be used.

Arguments made in connection with Whiteside, above, apply equally to claim 15 and its dependents.

Accordingly, Applicant respectfully submits that claim 15 is patentable over Techiera in view of Waugh in view of Whiteside. As claims 19-25 depend from claim 15, these dependent claims necessarily include all the elements of the base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references at least for the same reasons.

Claim 26 and Dependents

Arguments made with respect to Techiera, Matsen, and Whiteside, apply equally to claim 26.

In addition, claim 26 has been amended herein to clarify the invention, reciting, *inter alia*, cutting away a portion of bone of the joint...aligning a cutting guide member with a bone of the joint, the guide member having opposite ends with a transverse dimension which is less than the width of a portion of bone to be cut away, and angularly disposing the cutting tool along the guide surface in order to cut a section of the bone wider than the width of the guide, the swath of the angularly disposed cut being formed at an angle to the long dimension of the incision, and defining a width substantially greater than the width of the incision, at least a portion of said cut being located in the interior of the body with respect to the incision.

These claimed elements are not disclosed or suggested in the prior art. Accordingly, Applicant respectfully submits that claim 26 is patentable over Techiera in view of Waugh in view of Whiteside. As claims 27-33 depend from claim 26, these dependent claims necessarily include all the elements of the base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejections.

New Claims

Claims 34-36 have been added to clarify the invention, specifying in claim 34 that the guide is less wide than the width of the incision, in claim 35 that the swath of the angularly disposed cut is formed at about right angles to the long dimension of the incision, and in claim 36 that the joint is a knee, and the longest dimension of the incision is about 10 cm or less.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-012-1A).

Respectfully submitted,

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